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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,450	12/05/2003	Christina Khoo	7129-00	1031

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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,450	KHOO ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination filed August 15, 2005 has been received and entered into the case. Claims 15-20 have been added. Claims 1 and 14 have been amended. Claims 1-20 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have entered the limitation "wherein the mammal is selected from the group consisting of mammals *other than* hound dogs, herding dogs, and sporting dogs" in claims 16 and 18-20. An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). The specification, as originally filed, does not exclude hound dogs, herding dogs, or sporting dogs, rather it clearly states that the composition and method is to be useful for all mammals. Though applicants examples are directed towards felines, while this provides disclosure of non-canine mammals, it does not provide written description for the presently entered negative limitation "other than hound dogs, herding dogs, or sporting dogs." There is not sufficient support in the disclosure as originally filed for this

limitation; thus it is being considered new matter. The introduction of claim changes which involve narrowing the claims by introducing elements or limitations (including negative limitations) which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996). Applicant is required to cancel the new matter in the reply to this Office Action.

Information Disclosure Statement

The search report and written opinion of PCT/US04/40679 have been considered, but the search report and written opinion will not be listed on any patent resulting from this application because they are not separately published references. The cited references listed on the search report were considered, but only those separately listed on the PTO/SB/08A and 08B form will be listed on any patent resulting from this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089), and Klimberg et al (*Arch Surg*, 1990).

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-3 fatty acids, in the amount of 0.2%; antioxidants; and glutamine (See col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'). The

'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See col. 11, ln 18-28). Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress (such as bouts of diarrhea). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animals' diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the diet in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells (See, e.g. Shields, Jr. et al, col. 12, ln 11-22).

Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals, and therefore their inclusion in the diet (col. 5, ln 65- col. 6, ln 11). Shields, Jr. et al, however, do not teach a specific amount of antioxidants present in the diet. Wadsworth et al also

teach inclusion of vitamins and antioxidants, such as vitamins A and E, in amounts from 0-10% by weight (See col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without concern of over dosage. Therefore, though Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight.

Though Klimberg et al uses rats as the experimental animal, and Wadsworth et al dogs and cats, it would have been obvious to extend the results to include dogs, as described by Shields, Jr et al, because they are all mammals, dogs, cats and rats all have simple digestive tracts, and it is known that glutamine has similar beneficial effects on all three species, it is simply the amount of glutamine that is extrapolated from Klimberg et al and Wadsworth et al. For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al and Wadsworth et al, to include cats and other non-canine species, such as rats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts, and use of such composition for the management of diarrhea, would be obvious for use in dogs as well as non-canine mammals, such as cats and rats (Claims 1-20). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice,* 2002).

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine, can benefit an animal with a stressed

gastrointestinal tract (See Pg. 529, col. 2, and especially Pg. 533, col. 1). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See especially Pg. 533).

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega-3 fatty acids, and antioxidants, it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment potential of the diet. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would have been motivated to increase the amount of fermentable fiber, omega-3 fatty acids, and antioxidants, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega-3 fatty acids help to decrease inflammation, antioxidants promote immune response, and need to be replaced during bouts of diarrhea due to being flushed out, and glutamine has been found to provide energy for enterocytes during times of stress, boosting immune ability and GI health (See Chandler Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems (See Chandler Pg. 529, col. 2- Pg. 533, col. 1) (Claims 1-20). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed August 15, 2005 have been fully considered, but are not found persuasive. Specifically, applicant's argue that Shields, Jr. et al teaches away from the present invention and therefore cannot be used as the basis for the obviousness rejection. Applicants argue that because Shields, Jr. et al do not include glutamine in the diets of non-sporting dogs, working dogs, terrier dogs, and toy dogs (rather only in the diets of hound dogs, herding dogs, and sporting dogs), they are effectively teaching away from including glutamine in the diets of the other dogs. Applicant further argues that the examiner has used impermissible hindsight to arrive at the present obvious rejections. Applicant further argues that Chandler et al, like Shields, Jr. et al, does not teach the whole invention, but rather teaches away from the presently claimed invention because they teach that glutamine is more effective when added to the diet as part of whole intact proteins, and not as hydrolyzed proteins and amino acid supplements. Applicant also points out that Chandler et al does not teach the specified amounts as claimed in the current invention, and argues only hindsight would allow one to arrive at these specific concentrations.

In response to applicants' arguments that Shields, Jr. et al teach away from inclusion of glutamine in other dogs diets, based on the fact that they only include glutamine in the diets of hound dogs, herding dogs, and sporting dogs, it is noted that simply because Shields, Jr. et al do not teach including glutamine in the diets of all dog types, they certainly do not teach or suggest negative results when glutamine is fed to other dogs or animals. A reference merely not teaching every limitation does not constitute teaching away by that reference. See *In re Grasselli* 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983). Shields, Jr. et al focused on providing breed specific formulas, wherein the composition of each formula was intended to address problems known to be prevalent in those particular breeds. Shields, Jr. et al includes glutamine in the diets of herding dogs, hound dogs, and sporting dogs because they are known to be particularly susceptible to bouts of diarrhea or intestinal distress; Shields, Jr. et al teaches that

glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See col. 12, ln 11-22). Therefore, though Shields, Jr. et al only discloses including glutamine in the diets of dogs who are prone to gastrointestinal problems, it would have been obvious to one of ordinary skill in the art to feed glutamine to any breed of dog, or any mammal with a similar digestive tract (particularly other carnivores, such as cats) that is experiencing gastrointestinal inflammation or diarrhea, based on Shields, Jr. et al's teachings that glutamine is beneficial in stress situations (such as gastrointestinal stress).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant has failed to particularly point out what part of the rejection the examiner has relied on hindsight to construe.

In response to applicants' arguments that Chandler et al teaches away from the claimed invention, as Chandler et al teach glutamine present in whole proteins is more beneficial than hydrolyzed proteins and amino acid supplements, it is noted that the form of glutamine is not recited in the rejected claim(s) or in the specification. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, regarding Chandler et al's assertion that whole proteins provide more benefit than hydrolyzed glutamine or amino acid supplements, as above, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not

become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Therefore, even though Chandler et al teaches hydrolyzed proteins and amino acids are inferior to whole proteins, they still disclose the use of both whole proteins and hydrolyzed proteins and amino acids.

Finally, regarding the failure of Chandler et al to disclose the specific amounts and concentrations of ingredients claimed, it is well established in patent law that differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation, See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it is maintained that one of ordinary skill in the art would have been able, by routine experimentation, to optimize the concentrations and amounts of the disclosed ingredients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER